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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,423	02/08/2002	Minutza Leibovici	1662/51303	1722
26646	7590	01/22/2004	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	
DATE MAILED: 01/22/2004				

Please find below and/or attached an Office communication concerning this application or proceeding:

## Office Action Summary

**Application No.**

10/071,423

**Applicant(s)**

LEIBOVICI ET AL.

**Examiner**

Sharmila S. Gollamudi

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 16-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 16-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of Election of the Restriction Requirement received on October 23, 2003 and Preliminary Amendments received on December 24, 2004 is acknowledged. Claims 1 and 16-35 are pending in this application. Claims 2-15 are withdrawn as being drawn to the non-elected invention.

#### ***Election/Restrictions***

Applicant's election with traverse of the Restriction Requirement is acknowledged. The traversal is on the ground(s) that the restricted groups are related and do not cause an undue burden. This is not found persuasive because Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention I is the process of making a compound and the compound made, which is different from a invention II wherein the pharmaceutical composition containing the compound has a different effect and function than invention I. Furthermore, the art cited demonstrates that torsemide modification II is incorporated into pharmaceutical compositions without the compound being made by the instant process.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 16-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,482,417. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:**

Instant application claims a high purity torsemide modification II. The dependent claims recite a stable product that does not rearrange over time for at least three months. Further, the dependent claims recite particle sizes of 200, 100, and 50 microns.

US patent claims a pharmaceutical composition comprising torsemide modification that does not rearrange over time. The dependent claims recite a stable product that does not rearrange over time at least for three months. Further the dependent claims recite particles sizes of 200, 100, and 50 microns.

The instant application is obvious over US patent since instant claims have open-claim language wherein the product can be mixed with other ingredients; therefore the scope of the claims can include pharmaceutical excipients used in pharmaceutical compositions.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1 and 16-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The term "high purity" in claims 1 and 16-35 is a relative term, which renders the claim indefinite. The term "high purity" is not defined by the claim and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "does not substantially change over time" is also a relative term since the claims do not define what the time frame is or how much "substantially" encompasses.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 16, 17, 18, 19, 20, 21, 22, 26, 27, 28, 29, 30, 31, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Aronhime et al (6,465,496).**

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Aronhime et al discloses torsemide polymorphs. The reference discloses the process of preparing torsemide Dupont form 2 (modification II) and the final torsemide modification II. See example 2.

\*Note: The prior art reads on the claim that recite "high purity" since the degree of purity is not included. Further, the art reads on "torsemide modification II does not substantially rearrange over time" since the claims do not include a time frame. Claim 26 is a product-by-process and patentability is based on the product itself. In regards to claim 19 and 29, the instant claims are not distinguishable over the prior art since the prior art teaches the same process of making the modification; therefore the product yielded would have the same characteristics.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 16-18, 20-28, and 30-35 are rejected under 35 U.S.C. 102(a) as being anticipated by Dreckmann-Behrendt (5914336).**

Dreckmann-Behrendt discloses an oral tablet that contains 10% torsemide modification II in a tablet (Note example 5). Further, Dreckmann-Behrendt discloses the particle size of torsemide. (Note col. 3, lines 43-58). The reference teaches different doses according to dosage form and the use of torsemide as a diuretic and treatment of edema (col. 4, lines 35-60).

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\*Note: The prior art reads on the claim that recite "high purity" since the degree of purity is not included. Further, the art reads on "torsemide modification II does not substantially rearrange over time" since the claims do not include a time frame. Claim 26 is a product-by-process and patentability is based on the product itself.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aronhime et al (6,465,496) in view of Crenshaw et al (4,380,638).**

Aronhime et al teaches torsemide polymorphs. The reference teaches the preparation of torsemide Dupont form 2 (modification II) wherein a base is added to a suspension of torsemide in water until the pH has reached 10. The solution is then filtered and then ethanol is added while stirring. Acetic acid is added to the solution until the pH has reached 6. Finally the white solid is filtered, washed, and dried. See

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example 2. Aronhime also teaches the process of making torsemide II from amorphous torsemide. See column 4, lines 24-30. The reference teaches suitable solvents such as water, ethanol, propanol, isopropanol, etc. See column 5, lines 15-20. The torsemide forms may be used in pharmaceutical composition. See column 10, lines 50-60.

Aronhime et al do not teach acetonitrile as the solvent.

Crenshaw et al teach inert solvents include acetonitrile, methanol, ethanol, isopropanol, etc. See column 13, lines 44-49.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Aronhime et al and Crenshaw et al since it Crenshaw teaches the equivalency of the instant solvent and Aronhime's solvents. Therefore, it is prima facie obvious for a skilled artisan to substitute one solvent for another equivalent solvent with reasonable expectation of success since the solvents are taught to be functionally equivalent in the art.

### ***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

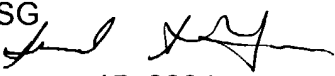
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

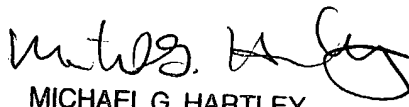


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

  
January 15, 2004

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER